National Institutes of Health

ERA Status Report: Design and Implementation Status of the NIH Commons

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NIH ERA COMMONS STATUS REPORT

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Introduction

This document represents a further update on the NIH electronic research administration (ERA) initiative. Previous status reports appeared in various editions of the NIH Guide for Grants and Contracts as detailed below:

- Volume 23, Number 44, December 16, 1994;
- Volume 24, Number 14, April 14, 1995;
- Volume 24, Number 40, November 24, 1995;
- Volume 25, Number 23, July 12, 1996, and
- Volume 26, Number 17, May 23, 1997.

Electronic Research Administration

Improving stewardship is a prime ongoing objective at the NIH in the administration of grants and contracts awarded to support research at universities and other research facilities around the Nation. Improving the efficiency of various administrative business processes and introducing more efficient ways to communicate relevant information between the NIH and grantee/contractor organizations will maximally leverage appropriations devoted to research, and thereby contribute directly to the productivity of the Nation's medical research enterprise. In addition to pursuing reinvention activities to improve research administration processes, the phenomenal advances and almost constant changes in Information Technology (IT) are also being exploited at the NIH to improve stewardship of awards.

NIH is currently devoting substantial IT-related resources in the design, development and deployment of an electronic research administration (ERA) system. This ERA system will greatly facilitate preparation of grant applications by research investigators, processing of applications by NIH staff, and management of awards by grantee organizations and NIH staff.

ERA System Design: IMPAC II and the NIH Commons

The foundation of this ERA system is two Oracle™ databases with associated software to allow respective users to submit and retrieve selected information needed to support the entire grants administration life cycle. Using this database technology in combination with user-friendly interfaces will permit timely, fully electronic communication between extramural grantee "business partners" and cognizant NIH staff responsible for stewardship of awards.

At the heart of the ERA system is the database the serves as the repository for the grant application and award-related records. This database, IMPAC II, is populated with grant records that can be acted upon solely by authorized NIH staff to conduct grants administration functions. Accordingly, interfaces that directly link to IMPAC II allow for NIH staff to refer newly received

applications for receipt and referral to study sections, to evaluate programmatic and grants management-related aspects of pending applications, to process noncompeting renewal applications, and to make awards.

The NIH Commons

As a means to serve the ERA requirements for grantees to submit, as well as monitor the status of information contained in IMPAC II, as second database has been incorporated into the ERA system. This second database, the NIH Commons, has been included distinct from IMPAC II both to ensure the security of information in IMPAC II, and to most efficiently accommodate the varied and extensive set of interface requirements needed by the grantees. While IMPAC has been designed to support a relatively controlled population of NIH staff users, the Commons must support grantees affiliated with any of a broad spectrum of grantee organizations having varied IT resources and user sophistication. This diverse population must be provided with secure, authenticated access to only their records, as well as be given some flexibility in how they choose to communicate with the NIH ERA system.

To support the major aspects of the grants administration life cycle, the Commons software is being scripted to include:

- submission of investigator-initiated competitive grant applications (type 1 and 2), noncompeting renewals (type 5), and fellowship applications;
- maintenance of contact information for all NIH grantee organizations and investigators;
- monitoring of the status of active and pending grants (including review dates, scores, and application summary statements);
- administration of trainee activities including appointment, reappointment, termination and payback;
- electronic notification to the grantee organization of grant award;
- a full function search of awarded research project abstracts; and
- submission and comprehensive tracking of extramural invention reports.

NIH is taking a well-documented, methodical approach to designing the portions of the ERA system that will support these varied business processes. To accommodate the broadest set of extramural user interface requirements, the Commons will employ secure Web-based interfaces. Software behind the interfaces for each of these activities will provide all necessary functionality for services such as security, auditing, record submission, updating, modification, notification and in some instances deletion. The rapid advances in Internet technology have made this approach highly feasible, while cost-effective and well received by the broadest spectrum of extramural grantee/contractor organizations.

<u>Commons Data Standards and Formats</u>

There exist two principle objectives of the Commons design that will ensure that the system is compatible with the greatest number of grantee organizations. First, all Commons software applications are being built upon well-documented data standards. The most notable of these is the public standard for grants administration, the American National Standards Institute (ANSI) 194 transaction set. By invoking the use of this data dictionary for all grants administration transmissions, both the grantee organization, sending the information, and the government agency, receiving the information, will be assured of successful communication. Similar standards are being employed for all business process transactions being developed in the Commons system.

The second Commons design objective is to maintain flexibility in the interface requirements available to Commons grantee organization users. In order for the NIH to accommodate a range of grantee organizations with disparate information technology infrastructures, the Commons will support three well-known transmission formats. Grantee organizations with substantial database systems wishing to interface with the Commons via computer-to-computer transmissions will be able to employ two standard datastream formats: Electronic Data Interchange (EDI), and/or Hypertext Markup Language (HTML). By contrast, other organizations that do not wish to employ computer-to-computer transmissions will be able to exchange information using basic Internet connectivity, using standard Web browser technology exchanging browser-derived HTML files. Details as to how these formats have been incorporated into specific Commons interfaces are described below.

Electronic Submission of Competing Grant Applications

Electronic Data Interchange (EDI)

Under a Department of Energy (DOE) Cooperative Agreement, the NIH along with several Department of Defense (DoD) agencies participated in 1996 and 1997 in a pilot study to test a new system for the submission of grant application information. These agencies and ten research institutions engaged to test the EDI standards developed collaboratively by the Federal agencies. Key administrative information in R01 grant applications, such as face page information, scientific abstract, certain budget items, and personal data for the Principal Investigator, were allowed to be submitted directly into NIH's Commons database, without intervening paper copies or manual re-keying of data. This pilot implementation commenced in October 1996 and continued through 1997. In 1998 and 1999 the pilot was expanded to include Federal Demonstration Partnership (FDP) organizations, and more aspects of the applications. The initial DOE pilot permitted the submission of only the application shell information (PHS form 398 pages AA, BB, DD, EE, Abstract, and Specific Aims). The FDP pilot expanded this information to include other pages (GG, HH, KK) as well as by allowing the Research Plan aspect of the application to be submitted as an Adobe PDF™ file. Other repetitive information required for the submission of the competitive application is linked to another portion of the Commons/IMPAC II databases that provide for Professional and Institutional Profile information (see Admin. System for details). Throughout 1998 and most of 1999, while the NIH Commons was available for receipt of EDI transactions, no grantee organizations were yet prepared to transmit data formatted in this way.

NIH's willingness to continue to support this technological alternative is mostly in deference to a small collection of grantee organizations who have been actively preparing to use EDI since the inception of the ANSI 194 standard. As of January 2000, one grantee organization was in a position to begin to send competitive applications using EDI. Unfortunately, given a recent change in the 194 standard, NIH is now in the midst of refining the translation software to accurately accept the data. Current plans target receipt by summer 2000. Further discussion of Commons EDI implementation can be found at http://grants.nih.gov/grants/era/era.htm .

HyperText Markup Language (HTML)

The first pilot implementation of the competitive application involved transmission of data via EDI formatted files. In an effort to provide grantee organizations with alternative modes of transmission of the same data, the NIH also chose to develop and pilot software that allows for the receipt of competitive application information via an HTML-formatted datastream. HTML is the language used to format data for use and visualization on the World Wide Web. Allowing for receipt of grant application information in this format affords grantee organizations who are developing research administration systems centered on Internet and HTML to retain data in this common format as they prepare to submit information to the NIH. It is important to emphasize that both EDI and HTML-formatted datastreams are based strictly on the same standard set of data elements. NIH began demonstration of the HTML prototype software in March 1997. During the Summer/Fall of 1998, FDP organizations were invited to submit the same extent of information via an HTML datastream or EDI datastream, including the Research Plan formatted as an Adobe PDF™ file. As with EDI, only a select few organizations have delineated plans and timeframes for having transaction sets of this type ready for transmission. Further discussion of Commons HTML datastream implementation can be found at http://grants.nih.gov/grants/era/era.htm .

Electronic Streamlined Noncompeting Award Process (e-SNAP)

e-SNAP Submission Via Interactive Web

In FY95, NIH instituted a simplified noncompeting award process (SNAP) for the majority of noncompeting continuation awards. Under SNAP, which applies to awards under the Expanded Authorities and Federal Demonstration Partnership, certain components of the noncompeting application are not required if there are no significant changes. (For more information on SNAP, see the NIH Guide for Grants and Contracts, October 27, 1995 and July 5, 1996.)

An ERA version of the SNAP process was also pilot tested to the DOE cooperative agreement organizations from Novermber, 1996 through 1997. "e-SNAP" is an interactive World Wide Web-based site for electronic submission of the SNAP information. Using the interface, authorized grantees are able to prepare for submission all required information. Then, through a separate site, grantee organization administrative official(s) can approve and then finally submit the application to the NIH to initiate the noncompeting award process. Upon receipt of the e-

SNAP submission into the NIH Commons the information undergoes validity checking and, if complete and uncorrupted, is immediately replicated into IMPAC II. Once in IMPAC II e-mail notifications indicate to cognizant NIH staff that they can evaluate the electronic application and if approved generate an electronic Notice of Grant Award back to the grantee and grantee organization administrative official(s). The second phase of e-SNAP deployment began in April 1999 to organizations participating in the Federal Demonstration Partnership (FDP). This version of the interactive Web-based e-SNAP included expanded functionality as suggested by the DOE cooperative agreement pilot organizations, including an enhanced functionality for routing of applications for approval by the grantee organization prior to submission to the NIH. Starting in July 1999, 15 of the FDP organizations were invited to begin to submit "live" e-SNAP applications for complete processing using this interactive Web software. As of February 2000 approximately 135 e-SNAP applications had undergone successful processing using this method.

A final major phase of functionality enhancement for non-competing award applications will be to include an interactive Web-based version of the software that will permit submission of applications that do not qualify for Streamlined Noncompeting Award Applications. These enhancements which will allow for the submission of, for example, complex Centers or Program Project grants is currently under development and will not be available for testing until late summer 2000.

e-SNAP submission via EDI or HTML Datastream

As an adjunct to e-SNAP via an interactive Web interface and as part of the FDP pilot deployment in the Spring of 1999, grantee organizations were given the alternative to submit the SNAP information using either EDI or HTML-formatted datastreams. As with the competitive applications, thus far only a small number of grantee organizations have indicated plans to submit e-SNAP applications using either of these datastream formats. Communications with several of these organizations suggest that e-SNAP transaction of either of these types will be forthcoming by summer 2000.

Electronic Reporting of Trainee Activities

Organizations that receive National Research Service Act (NRSA) Institutional research training grants must report on the appointment of trainee(s) supported under the grant. An ERA system interface is now being piloted that provides for the electronic submission of trainee appointment information. Like e-SNAP, the trainee appointment system takes advantage of the user-friendly benefits of the World Wide Web. In this case, the grant Training Program Director will submit required information through the secure Web interface. The pilot deployment of this portion of the ERA system started at the beginning of FY 96 with test data. "Live" data was received from eight grantee organizations in mid-FY 96, with NIH staff issuing electronic approvals. Expansion to include the FDP organizations is scheduled occur in the summer 2000, once final acceptance testing of the software has been completed. As of now, there are no plans to receive this information via either EDI or HTML datastreams.

Application and Award Status System

One of the obvious benefits of electronic communication is the ability to exchange time-sensitive information in a timely manner. Once critical administrative decisions or updates in information occur, the results of these actions can be communicated rapidly. This type of functionality for NIH extramural grants administration will be provided through the Commons Application and Award Status interface (the "Status" interface). In the first phase of the pilot test of Status, which began in March 1997, authorized users from the DOE cooperative agreement organizations were able to log onto a secure Web site where they could review basic aspects of the status of applications sent to the NIH, including pending review, review outcome, pending Advisory Council action, and award status. Grantee organization officials were able to view pending actions for all applications originating from their organization, while individual investigators were able to view only their applications.

The information flow that supports the NIH Commons Status interface involves acknowledgment by cognizant NIH staff of movement of each grant application through various process points. Such acknowledgments are noted via various IMPAC II interfaces. Once information regarding application status is changed in IMPAC II, the information is replicated once each day into the NIH Commons, so that grantees with authorization can reference the status changes.

The second phase of deployment of this portion of the Commons, which began in July, 1998, provided an expanded number of status milestones: from the initial receipt of either paper or electronic applications, through post-award administrative milestones such as target date(s) for noncompetitive renewals. In addition, the interface enabled research investigators to receive the text of Summary Statement(s) as well as priority score(s) and percentile rankings for any of their reviewed but yet to be awarded applications. Additionally, information contained in the Notice of Grant Award included special terms and conditions to be accessible through the secure Status interface. For summary statement, priority score and percentile information, it is important to note that this data is made available only to the Principal Investigator. Administrative Officials do not have access to this information, in recognition of Privacy Act considerations.

By October 1999 the Status system pilot was expanded beyond the FDP organizations. Additional grantees that had earlier expressed an interest in being able to review status using the Commons interface were invited to register for the system. By February 2000, approximately 3,200 users from 140 grantee organizations were registered and using the NIH Commons Status interface

Commons Admin. System

<u>ERA Accounts Administration</u>

On an annual basis, the NIH engages approximately 2,000 individual grantee organizations in grants/contract administration business processes. Some of these organizations employ from 100 to 1,000 investigators. Accordingly, for the NIH to be able to establish secure authenticated

electronic interactions and then track use and administration of accounts for this potentially overwhelming population of end users, the Commons design has employed a hierarchical administration of ERA user accounts. The Accounts Administration is administered through the Commons "Admin" interface. It permits senior administrative officials (Signing Officials) at each grantee organization to establish an account for the organization proper. Once this account is in place the Signing Officials are able to create secondary accounts for administrative officials, who can in turn create additional accounts for administrative staff and scientific staff. This permits the administrative officials - the individuals who have the best working knowledge of the workforce at their organization - to create and terminate accounts consistent with the status of investigators and administrative staff. Moreover, this hierarchy establishes the means by which applications can be approved prior to submission to the NIH.

Professional and Institutional Profile Administration

In addition to accounts administration, the Commons supports the establishment, monitoring and updating of two types of information profiles in order to relieve Administrative Officials, Principal Investigators and grant key personnel from having to re-key information. Principal Investigators can create and then access a Professional Profile File (PPF) to update their contact and biosketch information. In a similar way, authorized Grantee Organization officials are able to update the organizational contact information (Organizational Profile including administrative officials, financial, assurance and certification information). These establishment and timely updating of these respective profiles preclude re-keying such information for each submitted application, as must now be done with paper submissions.

Electronic Invention Reporting

The requirement for reporting of information pursuant to inventions derived from Federal funds is mandated in the Bayh-Dole Act. To support this requirement the NIH has developed an ERA system dubbed "Edison" which is designed to receive, store, sort, and provide reports on inventions, patents, licensing and invention utilization. As the first secure interactive Web site developed in ERA, it has been deployed in a full production version since the beginning of FY 96. The mission of ERA has been realized and can be documented by the Edison system. After one year, almost 50 percent of the grantee organizations that report inventions routinely to the NIH were using Edison. For each invention this represents the reduction from typically 15 cycles of paper correspondence to 3, dramatically shortening reporting time and effort, as well as making more information available in a usable format for grants administrators. In addition to continued recruitment of grantee organizations to use Edison, the next phase for this ERA system component sought to include other Federal research agencies in the deployment. Intially, seven additional agencies, including NSF, FDA, CDC, USDA/CSREES, NOAA, USAID and the Department of Commerce have made commitments to use the Edison system to support invention reporting by their grantees. The deployment of "Interagency Edison" commenced in the summer of 1997.

As of January 2000, now 11 agencies are now using Interagency Edison as a means to allow their grantee organizations to report inventions. Over 230 grantee/contractor organizations are now registered for Interagency Edison. For NIH supported inventions alone, in CY1999 over 2,000 new inventions were reported.

CRISP on the Web

The NIH awards database, Computer Retrieval of Information on Scientific Projects (CRISP), is a collection of research project abstracts and grant related information that spans nearly 25 years. Until 1998, the most sophisticated way to search for such information was via a "gopher" interface, limited to relatively simple queries. As part of the ERA initiative, a Web-based CRISP interface was developed to allow full text searching of research project abstracts and grantee organization information. This type of query interface has been demonstrated to vastly improve the ability to retrieve the most relevant sources of information to facilitate further research through inquiries by researchers, to provide useful information for the public, and to improve the efficiency of responses to inquiries issued by other agencies and Congress. The new CRISP Web interface was deployed to the general public in July 1998 covering awards made from 1985 to the present. As of January 2000 the interface was undergoing final testing to include award records back to 1972. Statistics indicate that the “CRISP on the Web” site is now visited average of over 35,000 times per week. The site has received several awards by IT industry groups.

NRSA Fellowships

The design and development of an interactive Web-based interface to support application and administration of NRSA Fellowships awarded by the NIH is underway. To ensure that all data requirements are being met, a first design effort focused on defining a full data dictionary for fellowship applications, as well as derived a full set of business process requirements. Interface design specifications have been completed, and interface coding began in February 2000. Barring any unforeseen delays, the interactive-Web fellowships interface should be ready for FDP pilot deployment by summer 2000, with production deployment for follow by the end of CY2000. In light of the fact that typical fellowship applicants do not have sophisticated database systems that would demand computer-to-computer transmission, no datastream version of the fellowship application software is being contemplated.

Commons deployment

The NIH Commons deployment has purposely been phased. Given the relatively radical change in day-to-day operations typically experienced by any organization as ERA is undertaken, it has always been felt that the extramural community would much better receive a controlled/phased deployment than fixed deadlines. Further, phased deployment: migration from limited pilots to expanded pilots to production has allowed the NIH to glean from feedback offered by a manageable number of users. The broad and diverse nature of the grant organization community

does not lend well to the creation of "Joint Application Development Teams" as was done for the design of IMPAC II. Instead, Commons design considerations were prototyped based on the initial definition of interface and user requirements. Further iterations of the design and interface implementation have been based largely on user experience. In this way, through the three major deployment phases detailed below, there have been six releases of ever-enhanced versions of Commons user interface software.

DOE Cooperative Agreement Pilot Deployment

The Commons was first deployed on a development computer platform in November, 1996. This platform was made accessible to 10 grantee organizations who had been selected to assist in the first pilot deployment. The organizations included:

- Fred Hutchinson Cancer Center
- Univ. of California, Los Angeles
- Pennsylvania State University
- University of Notre Dame
- Florida A&M University
- Ohio State University
- North Carolina State University
- Baylor College of Medicine
- Duke University
- Massachusetts Institute of Technology

This selection was based on participation in a DOE Cooperative Agreement in which NIH was formally involved. When each new function was completed and incorporated into the Commons, these 10 grantee organizations were invited to access and test the functionality. Deployment of the NIH Commons in this way allowed for iterative feedback from initial users. Such input proved invaluable to confirm the acceptability of the basic Commons design. Subsequent introduction of enhanced functionality has been determined in part by the outcome of the DOE pilot.

Deployment of the Commons Production Platform

In order for the deployment of the NIH Commons to be consistent with the plan summarized above, the Production Commons platform was put in service in May 1997 at http://www-commons.cit.nih.gov . The production platform is a Digital Equipment Corporation (DEC) Alpha™ 8400 computer located at, and supported fully by the NIH Center for Information Technology (CIT). Aside from the full production instance of the Commons, the platform is also runs a Commons demo site (http://commons-demo.cit.nih.gov) , being accessed by prospective Commons users to explore the Commons functionality.

FDP Pilot Deployment of Commons Software

The next phase of the deployment included approximately 65 grantee organizations participating in the Federal Demonstration Partnership (FDP). As with the deployment to DOE cooperative agreement organizations, the participating FDP organizations were expected to establish accounts for the purposes of submission of information, accessing the status of applications previously submitted to NIH, and establishing their professional and institutional profiles. The FDP pilot that commenced in July 1998 was divided into two phases; a first phase during which organizations could submit "test" transmissions that were not formally processed by NIH staff, and a second "live transmission" phase during which NIH staff have been able to finally process submitted applications. Throughout the FDP deployment, institutions have been submitting paper applications in parallel with electronic applications to ensure no interruption in application processing, in the event problems arise in the processing of the electronic applications.

Pre-Production Pilot of Commons Software

As was pointed out above for the Status interface, by October 1999 the FDP pilot was expanded to include approximately 150 grantee organizations. As of March 2000, approximately 140 organizations had registered for Commons use of the "Admin" and "Status" interfaces. The e-SNAP pilot has not yet been expanded to pre-production, pending the final testing of production-grade software that flawlessly replicates all application-related information from the Commons to IMPAC II.

Production Deployment of Commons Software

Once each of the Commons interfaces has been deemed acceptable with approximately 150 organizations using the software, and with all Commons/IMPAC II data transfer software completely tested and approved, a final production deployment will be put in place. It is anticipated that, barring any major problems, such a production deployment for many of the Commons interfaces will occur by the end of CY2000.